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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,279	07/18/2001	Kazumi Iijima	K0208-013	5027

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Patterson Belknap Webb & Tyler, LLP
Attention: I.P. Docketing
1133 Avenue of the Americas
New York, NY 10036

EXAMINER

AUGHENBAUGH, WALTER

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 06/16/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-9

Office Action Summary	Application No.		Applicant(s)	
	09/647,279		IIJIMA, KAZUMI	
	Examiner		Art Unit	
	Walter B Aughenbaugh		1772	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Acknowledgement of Applicant's Amendments

1. The amendments made in Claims 1-3 and 5 given on pages 1 and 2 of Paper #8 have been received and considered by Examiner.

WITHDRAWN REJECTIONS

2. The 35 U.S.C. 112, second paragraph rejection of claim 1, in regard to all of the reasons for the rejection with the exception of the indefiniteness of the structure pertaining to the question "is the 'luer lock portion' only the 'cylindrical space' or do the inner and outer cylinders comprise the 'luer lock portion'?" raised by Examiner in Paper #6, has been withdrawn due to Applicant's amendments in Paper #8.

3. The 35 U.S.C. 112, second paragraph rejection of claims 2-5 has been withdrawn due to Applicant's amendments in Paper #8.

4. The 35 U.S.C. 102(b) rejection of claim 1 as anticipated by Moncada et al. made of record in paragraph 7 on page 4 of Paper #6 has been withdrawn due to Applicant's amendments in Paper #8 and has been replaced with the new 35 U.S.C. 102(b) rejection of claim 1 as anticipated by Moncada et al. made of record in this Office Action (Paper #9).

5. The 35 U.S.C. 103(a) rejection of claims 2 and 3 over Moncada et al. made of record in paragraphs 9 and 10 on pages 5-6 of Paper #6 has been withdrawn due to Applicant's amendments in Paper #8 and has been replaced with the new 35 U.S.C. 103(a) rejection of claims 2 and 3 over Moncada et al. made of record in this Office Action (Paper #9).

6. The 35 U.S.C. 103(a) rejection of claim 4 over Moncada et al. in view of Porfano et al. made of record in paragraph 11 on pages 6-7 of Paper #6 has been withdrawn due to Applicant's

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amendments (to claim 1) in Paper #8 and has been replaced with the new 35 U.S.C. 103(a) rejection of claim 4 over Moncada et al. in view of Porfano et al. made of record in this Office Action (Paper #9).

7. The 35 U.S.C. 103(a) rejection of claim 5 over Moncada et al. in view of Lampkin made of record in paragraph 12 on page 7 of Paper #6 has been withdrawn due to Applicant's amendments in Paper #8 and has been replaced with the new 35 U.S.C. 103(a) rejection of claim 5 over Moncada et al. in view of Lampkin made of record in this Office Action (Paper #9).

REPEATED REJECTIONS

8. The 35 U.S.C. 112, second paragraph rejection of claim 1 in regard to the structure pertaining to the question "is the 'luer lock portion' only the 'cylindrical space' or do the inner and outer cylinders comprise the 'luer lock portion'?" raised by Examiner in Paper #6 has been repeated for the reasons previously made of record in paragraph 5 of Paper #6. The phrase that has been amended to "a luer lock portion comprising a cylindrical space formed by an inner peripheral surface of the outer cylinder and an outer peripheral surface of the inner cylinder" does not adequately address the question "is the 'luer lock portion' only the 'cylindrical space' or do the inner and outer cylinders comprise the 'luer lock portion'?" raised by Examiner in Paper #6.

NEW REJECTIONS

Claim Rejections - 35 USC § 102

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Moncada et al.

Moncada et al. teach a plastic syringe barrel (the combination of syringe barrel, item 84 and adapter, item 80, having a generally continuous surface at the junction of the syringe and the

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barrel and the adapter, see Fig. 5) for holding fluid comprising a nozzle portion (adapter body, item 20, Fig. 1 and 2 and adapter, item 80, Fig. 5) at the forward end of the plastic syringe barrel for permitting attachment of an extension tube or other device (needle mount, item 94 and hypodermic needle, item 96) in which an outer cylinder (flanges, item 116, Fig. 5 and corresponding unlabelled flanges in Fig. 1) and an inner cylinder (cylindrical portion, item 30, Fig. 1 and male Luer lock connector portion, item 106, Fig. 5) are formed (col. 3, lines 62-67, col. 4, lines 2-4, col. 5, line 48-col. 6, line 20). Moncada et al. teach that the adapter includes a connector for mounting a needle and a sleeve or needle guard (and therefore teaches that the nozzle portion is for permitting attachment of an extension tube or other device) (col. 2, lines 23-32). Moncada et al. teach a luer lock portion (the combination of items 108 and 116 and the space between items 108 and 116, Fig. 5) comprising a cylindrical space formed by an inner peripheral surface of the outer cylinder (item 116, Fig. 5) and an outer peripheral surface of the inner cylinder (item 108, Fig. 5). Moncada et al. teach that the inner cylinder (cylindrical portion, item 30, Fig. 1) has ears (item 34, Fig. 1) for securing a Luer lock portion (item 24, Fig. 1) which is continuous with the inner cylinder (item 30) into a cooperating Luer lock portion (col. 4, lines 4-6). Moncada et al. teach that the outside surfaces of the ears (item 34) include teeth (item 48) and that teeth or any other type of roughened surface are formed on the rear surface (item 50, Fig. 1) of the ears (item 34) (col. 4, lines 42-60 and Fig. 1 and 2). The ears, item 34 of Fig. 1, correspond to the ears, item 112 of Fig. 5 (col. 5, line 64-col. 6, line 6); therefore, Moncada et al. teach that all or part of an inner surface of the luer lock portion (the combination of items 108 and 116 and the space between items 108 and 116, Fig. 5) has a roughened surface.

The phrases “for holding fluid” and “for permitting attachment of an extension tube or other device” are intended use phrases that have been given little patentable weight since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987).

Claim Rejections - 35 USC § 103

10. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moncada et al.

Moncada et al. teach the plastic syringe barrel as discussed above.

In regard to claim 2, Moncada et al. teach that any frictional engaging means (including teeth or a roughened surface, col. 4, lines 45-50) may be positioned at any other location along the length of the adapter (col. 6, lines 19-23). Moncada et al. fail to explicitly teach that the inner peripheral surface of the outer cylinder, specifically, has a roughened surface. However, since Moncada et al. teach that the outside surfaces and rear surface (item 50) of ears (34 and 112) have teeth or any other type of roughened surface for increased frictional engagement between the ears and a cooperating female Luer lock portion (col. 4, lines 42-53) and that teeth or any other roughened surface may be positioned at any other location along the length of the adapter depending on the desired end use, one of ordinary skill in the art would have recognized to form teeth or any other type of roughened surface on the inner peripheral surface of the outer cylinder of Moncada et al. in order to enhance the frictional engagement between the outer cylinder and a cooperating female Luer lock portion and to consequently further enhance the frictional

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engagement between the [male] 'luer lock portion' as recited in instant claim 1 and the female luer lock portion of Moncada et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed teeth or any other type of roughened surface on the inner peripheral surface of the outer cylinder of Moncada et al. in order to enhance the frictional engagement between the outer cylinder and a cooperating female Luer lock portion and to consequently further enhance the frictional engagement between the [male] 'luer lock portion' as recited in instant claim 1 and the female luer lock portion of Moncada et al.

In regard to claim 3, Moncada et al. teach a Luer lock connector having ears (item 122) on the male Luer lock portion of the needle mount (item 94) and threads (item 124) on the female Luer lock portion (item 118) (col. 6, lines 7-16 and Fig. 5). Moncada et al. teach that the threaded engaging means or other engaging means may be positioned at any other location along the length of the adapter (item 80) (col. 6, lines 19-23). The portion of the female Luer lock portion (item 118) that has threads (item 124) corresponds the outer cylinder as claimed; Moncada et al. therefore teach that the inner peripheral surface of the outer cylinder contains a helically continuous screw thread.

Moncada et al. fail to explicitly teach that the surface of the screw thread or screw root portion formed between adjacent ridges of the screw thread specifically has a roughened surface.

However, since Moncada et al. teach that the outside surfaces and rear surface (item 50) of the ears (item 34) have teeth or any other type of roughened surface for increased frictional engagement between the ears and a cooperating female Luer lock portion (col. 4, lines 42-53) and that the threaded engaging means or other engaging means may be positioned at any other

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location along the length of the adapter (item 80) (col. 6, lines 19-23), one of ordinary skill in the art would have recognized to have formed threads (item 124) on the inner peripheral surface of outer cylinder (item 116) when required depending on the desired end use of the product as taught by Moncada et al. and to have formed teeth or any other type of roughened surface on the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed teeth or any other type of roughened surface on the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moncada et al. in view of Porfano et al.

Moncada et al. teach the plastic syringe barrel as discussed above. Moncada et al. fail to teach that the material of the plastic syringe barrel is cyclic polyolefin resin. Porfano et al., however, teach a syringe barrel (item 12) that is made of cyclic polyolefin copolymer resin (col. 6, lines 48). Porfano et al. teach that cyclic polyolefin copolymers are suitable plastics to use as the syringe barrel material since cyclic polyolefin copolymers typically do not require a clarifying agent (col. 6, lines 46-48). Therefore, one of ordinary skill in the art would have recognized to use cyclic polyolefin copolymer resin as the material of the syringe connector

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structure of Moncada et al. since cyclic polyolefin copolymer resin is a notoriously well known material for syringe barrels as taught by Porfano et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used cyclic polyolefin copolymer resin as the material of the syringe connector structure of Moncada et al. since cyclic polyolefin copolymer resin is a notoriously well known material for syringe barrels as taught by Porfano et al.

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moncada et al. in view of Lampkin.

Note, however, that the limitation "said roughened surface is blast treated" is a method limitation that has not been given patentable weight since the method of forming the plastic syringe barrel is not germane to the issue of patentability of the plastic syringe barrel itself.

Moncada et al. teach the plastic syringe barrel as discussed above. Moncada et al. fail to explicitly teach that the roughened surface is blast treated. Lampkin, however, discloses a syringe (item 10) with tubular barrel (item 11) constructed of thermoplastic material (col. 2, lines 32-36). Lampkin discloses that a surface of the syringe is roughened by sand blasting or other roughening processes. One of ordinary skill in the art would recognize to blast treat the plastic syringe barrel of Moncada et al. to form the roughened surface of Moncada et al. since blasting is a notoriously well known roughening process as taught by Lampkin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have blast treated the plastic syringe barrel of Moncada et al. to form the roughened surface of Moncada et al. since blasting is a notoriously well known roughening process as taught by Lampkin.

ANSWERS TO APPLICANTS ARGUMENTS

13. Applicant's arguments on page 4 of Paper #8 regarding the 35 U.S.C. 102(b) rejection of claim 1 as anticipated by Moncada et al. have been fully considered but are not persuasive.

Applicant argues that claim 1 requires "a plastic syringe barrel with a luer lock portion that has a roughened inner surface" and that Moncada et al. teach that the adapter, not the syringe, has a roughened inner surface. Claim 1 reads "a plastic syringe barrel for holding fluid comprising: a nozzle portion at the forward end of the plastic syringe barrel... and a luer lock portion... wherein all or part of an inner surface of said luer lock portion has a roughened surface". The adapter (items 20 and 80) of Moncada et al. is "a nozzle portion at the forward end of the plastic syringe barrel for permitting attachment of an extension tube or other device" as required by claim 1. The nozzle portion (adapter of Moncada et al.) is a component of the plastic syringe barrel ("a plastic syringe barrel for holding fluid, comprising a nozzle portion..."), and therefore, the plastic syringe barrel of Moncada et al. has a "luer lock portion that has a roughened inner surface" since the adapter of Moncada et al., a component of the plastic syringe barrel as claimed, has a "luer lock portion that has a roughened inner surface". Moncada et al. teach that a generally continuous surface is present at the junction of the syringe barrel 84 and the adapter 80" (col. 5, lines 48-52 and Fig. 5); therefore, the adapter is an extension of the syringe barrel and Examiner therefore interprets the adapter of Moncada et al. to be a component of the syringe barrel.

14. Applicant's arguments on pages 5-6 of Paper #8 regarding the 35 U.S.C. 103(a) rejection of claim 2 over Moncada et al. have been fully considered but are not persuasive.

Applicant argues that Moncada et al. teaches away from the instant application because an object of Moncada et al. is to “enable needle sleeves and guards to be used on unmodified syringes and needle fittings”. However, Moncada et al. does indeed teach that the adapter (a component of the plastic syringe barrel as discussed in the Examiner’s response to Applicant’s arguments in regard to the rejection of claim 1 in this Office Action) has a roughened surface. Applicant points out that Moncada teaches “the advantages of an adapter that can be used with unmodified syringes”. While Moncada et al. solely names item 84 a syringe barrel, claim 1 of the instant application requires that the adapter (item 80) of Moncada et al. be a component of the “plastic syringe barrel” as claimed by Applicant: the adapter of Moncada et al. corresponds to the nozzle portion as claimed by Applicants as discussed in the Examiner’s response to Applicant’s arguments in regard to the rejection of claim 1 in this Office Action.

Applicant’s argument that Moncada et al. never suggests that the female luer lock portions in the syringe and in the adapter taught by Moncada et al. should have roughened surfaces is irrelevant because Moncada et al. teaches that any surface of the adapter (a component of the plastic syringe barrel as claimed) could have a roughened surface (col. 6, lines 19-23), the location/s of which being a matter of the intended use and/or desired end result.

15. In response to Applicant’s statement that “the Examiner neither relies on or cites anything in either Porfano or Lampkin that teaches or suggests a roughened surface on the luer lock portion of a syringe”, Moncada et al. teaches a roughened surface on the luer lock portion of the adapter of Moncada et al., which is a component of the “plastic syringe barrel” as claimed by Applicant as discussed in the Examiner’s response to Applicant’s arguments in regard to the rejection of claims 1 and 2 in this Office Action.

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Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B Aughenbaugh whose telephone number is 703-305-4511. The examiner can normally be reached on Monday-Friday from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 703-308-4251. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

wba
06/06/03

WBA


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

6/13/03